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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/942,024

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Lance E. Steward

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08/18/2006

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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,024

Applicant(s)

STEWART ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-61 and 63-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-61 and 63-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-31-2006 has been entered.

The amendment and response filed on 5-31-2006 are acknowledged. Claims 35-37, 39-40, 43-47, 49-52, 54-61, 64-65, 68-72, 79, 82-84, 90-94 and 96-99 have been amended. Claim 62 has been canceled. Claims 101-123 have been added. Claims 35-61 and 63-123 are pending and currently under examination. Claims 37 and 84 have been amended to read on the elected invention and as such have been rejoined.

Claim Rejections Withdrawn

The rejection of claims 68-72 and 90-94 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to: particularly define the acceptor; the steps lacking antecedent basis; and not clearly defining the conditions is withdrawn in light of the amendment thereto.

The rejection of claims 35, 36 and 38-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the amendment thereto.

The rejection of claims 60-61, 63-68 and 74-78 under 35 U.S.C. 102(e) as being clearly anticipated by Schmidt et al. (U.S. Patent 6,762,280, with priority to the BoNT/A peptide FRET

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substrate assay for detection of BoNT/A as cited in the provisional 60/235,050 filed September 20, 2000) is withdrawn in light of the amendment thereto.

The rejection of claims 69, 70 and 73 under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent 6,762,280, with priority to the BoNT/A peptide FRET substrate assay for detection of BoNT/A as cited in the provisional 60/235,050 filed September 20, 2000) in view of Clegg et al. (Current Opinion in Biotechnology 6:103-110, 1995) is withdrawn in light of the amendment thereto.

The rejection of claim 72 under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent 6,762,280, with priority to the BoNT/A peptide FRET substrate assay for detection of BoNT/A as cited in the provisional 60/235,050 filed September 20, 2000) in view of Siegel et al. (STKE, June 27, 2000 of record) is withdrawn in light of the amendment thereto.

The rejection of claim 71 under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent 6,762,280, with priority to the BoNT/A peptide FRET substrate assay for detection of BoNT/A as cited in the provisional 60/235,050 filed September 20, 2000) in view of Auwerx et al. (U.S. 2003/0104975, published June 5, 2005 with priority to 60/297,772, filed June 14, 2001) is withdrawn in light of the amendment thereto.

The rejection of claims 60-61, 63-70, 73-83, 85-92 and 95-100 under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent 5,965,699) in view of Mahajan et al. (Chemistry and Biology, 6:401-409, 1999) and Clegg et al. (Current Opinion in Biotechnology 6:103-110, 1995) is withdrawn in light of Applicant's arguments and the amendment thereto.

The rejection of claims 72 and 94 under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent 5,965,699) in view of Mahajan et al. (Chemistry and Biology, 6:401-

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409, 1999) and Clegg et al. (Current Opinion in Biotechnology 6:103-110, 1995) and in further view of Siegel et al. (STKE, June 27, 2000, of record) is withdrawn in light of Applicant's arguments and the amendment thereto.

The rejection of claims 71 and 93 under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent 5,965,699) in view of Mahajan et al. (Chemistry and Biology, 6:401-409, 1999) and Clegg et al. (Current Opinion in Biotechnology 6:103-110, 1995) and in further view of Auwerx et al. (US 2003/0104975) is withdrawn in light of Applicant's arguments and the amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 35-39, 41-42, 44-45, 47-49, 53, 60-61, 63-64, 66-73, 78-82, 84-86, 88-95, 100-102, 106-107 and 115-119 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 61-63, 71-74, 76-86 and 95-97 of copending Application No. 10/261,161 for the reasons set forth in the previous Office action in the rejection of claims 35-36, 38-39, 41-42, 44-45, 47-48 and 53.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Contrary to Applicant's assertion, the first filed application does not constitute the "first patent" recited in the MPEP 804. The term "first patent" refers to the first allowed application.

Consequently, the rejection is deemed proper and is maintained.

New Grounds of Rejection

35 USC § 112, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-61 and 73-123 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Applicant has amended the claims 35-36, 60-61, 79, 83 and 104-105 to recite “cleavage site region...” This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-61 and 73-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-36, 60-61, 79, 83 and 104-105 are rendered vague and indefinite by the use of the phrase “cleavage site region”. It is unclear what is meant by said term, as it not disclosed in the specification as originally filed. As said phrase has not been defined it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ROBERT A. ZEMAN
PRIMARY EXAMINER

August 15, 2006